EXHIBIT B

Civamide Cream

Phase II study (#1103-5651-01) This Phase II trial was a double-blind, randomized, vehicle-controlled, parallel-group, dose-ranging, multicenter study conducted to evaluate the safety and efficacy of topical Civamide Cream, 0.01% and Civamide Cream 0.075%, in subjects with long-standing painful osteoarthritis of the knee. There were 13 sites that enrolled a total of 178 subjects, males and females 30 to 85 years of age, with long-standing painful osteoarthritic pain in the Target Knee. Study drug was self-administered topically four times daily for 2 weeks.

The primary efficacy variables were the Visual Analogue Scale (VAS) for OA Pain Severity, the Tenderness Assessment (palpation and passive range of motion), the Physician's Global Evaluation, and the Subject's Global Evaluation. The secondary efficacy variables were the VAS for Severity of Pain's Interference with Sleep, the Timed 50 Foot Walk, and the Daily Activity Assessment. The safety and tolerance variables were Application Site Assessments, serum chemistry, hematology, urinalysis, Musculoskeletal Examination, and Adverse Experience reporting.

A statistically significant overall effect was observed among treatment groups in the VAS for OA Pain Severity at Day 8 and at Day 14 ($p<0.05$). Statistically significant pairwise differences between treatment groups were not detectable due to insufficient statistical power; however, subjects treated with Civamide Cream, 0.075% showed the greatest response in pain relief. The Daily Activity Assessment measuring comfort level in performing daily activities showed statistically significant overall effect for treatment at Days 8 and 15 ($p=0.020$ and $p=0.008$), respectively). A statistically significant increase in comfort level ($p<0.017$) was noted at Day 8 for Civamide Cream, 0.075%, vs Civamide Cream, 0.01%, and at day 14 when comparing Civamide, 0.075%, to the low dose and to vehicle cream. Although not statistically significant, subjects treated with Civamide Cream, 0.075%, showed greater improvement in pain frequency and/or intensity measured via PGE and SGE as compared to subjects treated with Civamide Cream, 0.01%, or vehicle. Civamide Cream 0.01% did not produce any statistically significant effects as compared to vehicle in the VAS for OA Pain Severity, the PGE and the SGE. In addition, no statistically significant differences existed among treatment groups in the Tenderness Assessment, the VAS for Severity of Pain's Interference with Sleep or the Timed 50-foot Walk.

Analysis by age group indicated that Civamide Cream, 0.075%-treated subjects aged 65 years and older exhibited statistically significant reductions in OA pain as measured via VAS by Day 14 ($p=0.029$). These subjects were also evaluated as having less intense and/or frequent pain at Day 8 as shown in the PGE ($p=0.034$) and Day 14 as shown in the SGE ($p=0.04$). Investigators reported that many patients reported relief of their OA pain for periods as long as 2-4 months after completing the study.

Application site reaction, the most frequently reported adverse experience was reported by 84 subjects (0.075%=51; 0.01%=25; veh=8). No serious and unexpected adverse experiences were considered attributable to study drug treatment.

Phase II study (#1103-5651-03) This Phase II trial was a double-blind, randomized, vehicle-controlled, parallel-group, multicenter study conducted to evaluate the safety and efficacy of Civamide Cream, 0.075%, in subjects with osteoarthritis of the knee. There were 8 sites that enrolled 151 subjects. Males and females, at least 40 years of age with primary or post-traumatic osteoarthritis of the Target Knee. Study medication consisted of Civamide Cream 0.075% and a vehicle cream not containing civamide. Study drug was self-administered topically four times daily for 4 weeks.

The primary efficacy variables were the VAS for OA Pain Severity, the Physician's Global Evaluation, the Subject's Global Evaluation, and the Tenderness Assessment. The secondary efficacy variable was the Daily Activity Assessment. The primary safety variable was Adverse Experience reporting.

Statistically significant effects in favor of Civamide Cream 0.075% were seen at Day 28 for all four primary efficacy variables. Civamide-treated subjects experienced a 57.6% reduction in VAS for OA Pain compared to a 41.9% reduction in vehicle-treated subjects (p=0.044). Additionally, statistically significant differences between treatments was first observed at Day 21, with Civamide Cream 0.075%-treated subjects showing a 53.5% reduction in VAS pain, compared to a 36.9% reduction in vehicle-treated subjects (p=0.003). Civamide Cream 0.075%-treated subjects also had significantly less tender Target Knees than their vehicle-treated counterparts on Day 14 (p=0.048) and Day 28 (p=0.003). Additionally, a greater percentage of Civamide Cream 0.075%-treated subjects were evaluated as "improved" in both the PGE and SGE (85% of Civamide-treated subjects vs 75% of vehicle-treated subjects for the PGE; 81% of Civamide-treated subjects vs 72% vehicle-treated subjects for the SGE). These results were statistically significant in favor of Civamide Cream 0.075%-treated subjects on Day 28 in both the PGE (p=0.017) and the SGE (p=0.011).

Onset of action was defined as the visit at which a 30% or more change from baseline in VAS scores was first observed. At Day 7, Civamide-treated subjects experienced a mean percent change from baseline of 38.7%; therefore, onset of action for Civamide was determined to be Day 7. Similarly to study #1103-5651-01, many patients reported continued relief of OA pain for as long as 4 months following discontinuance of study medication.

Application site reaction was the most commonly reported adverse experience; the majority of these reports (93%) were mild to moderate in nature. A transient burning sensation, generally at the application site, was the most frequently reported application site reactor. No systemic adverse experiences were considered attributable.